UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

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|---|---|---|
| UNITED STATES OF AMERICA, | ) | |
| | ) | CASE NO.: 3:22-CV-00512-KM |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | JUDGE MEHALCHICK |
| | ) | |
| PETER J. BADDICK, III., DO. | ) | |
| | ) | ELECTRONICALLY FILED |
| Defendant. | ) | |

**AMENDED COMPLAINT**

Plaintiff, the United States of America, by its attorney, Gerard M. Karam, United States Attorney for the Middle District of Pennsylvania, alleges as follows:

## I. INTRODUCTION

1. This is a civil fraud action brought by the United States of America against Dr. Peter J. Baddick, III, under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, to recover treble damages and civil penalties resulting from false and/or fraudulent claims for controlled substance prescriptions that Dr. Baddick caused to be submitted to the Medicare Program and TRICARE.

## II. JURISDICTION AND VENUE

2. The United States brings this action pursuant to the False Claims Act (FCA), 31 U.S.C. §3729, *et seq*.

3. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § § 1331 and 1345.

4. The Court may exercise personal jurisdiction over the defendant pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the defendant can be found in and has transacted business within the Middle District of Pennsylvania.

5. Venue is proper in the Middle District of Pennsylvania under 31 U.S.C. § 3732(a), because Dr. Baddick's actions caused DiPietro's pharmacy, located in the Middle District of Pennsylvania, to submit false and/or fraudulent claims to the Medicare Program and TRICARE in violation of 31 U.S.C. § 3729.

## III. THE PARTIES

6. Plaintiff is the United States of America.

7. Defendant Dr. Peter J. Baddick, III, is an individual residing in the Commonwealth of Pennsylvania.

8. Upon information and belief and based upon documents provided by Dr. Baddick and/or his counsel, in 1994 Dr. Baddick received a medical degree from the Philadelphia College of Osteopathic Medicine.

9. Upon information and belief and based upon documents provided by Dr. Baddick and/or his counsel, in 1995 Dr. Baddick received an Osteopathic Physician and Surgeon license (No. OS008960L) from the Commonwealth of Pennsylvania.

10. Upon information and belief and based upon documents provided by Dr. Baddick and/or his counsel, at all times relevant to this Complaint, Dr. Baddick did not hold any board specialty certifications.

11. In 1996, Dr. Baddick applied for and received DEA authorization to prescribe Schedule II, III, IV and V controlled substances.

12. At times relevant to this Complaint, Dr. Baddick practiced family medicine and/or internal medicine within the Middle District of Pennsylvania.

## IV. LEGAL AND REGULATORY FRAMEWORK

### A. THE CONTROLLED SUBSTANCES ACT & SUBSYS

13. The Controlled Substances Act (CSA) governs the manufacture, distribution, and dispensation of controlled substances in the United States. In order to prevent any person from diverting controlled substances from legitimate to illegitimate uses, the CSA established a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.

14. The CSA classifies controlled substances into five schedules: I, II, III, IV and V. 21 U.S.C. § 812(c); 21 C.F.R. § 1308.01.

15. Schedule II controlled substances are drugs that have an accepted medical use but have a high potential for abuse which may lead to severe psychological or physical dependence. 21 U.S.C. § 812(b)(2).

16. The CSA classified the TIRF medication, Subsys as a Schedule II drug.

## B. SUBSYS, TIRF MEDICATIONS AND THE TIRF-REMS PROGRAM

17. Subsys was first approved for use by the FDA in January 2012. The drug was approved only for patients with an *active cancer diagnosis* who were *opioid tolerant* and who experienced *breakthrough cancer pain*.

18. Subsys is part of a special class of drugs, known as transmucosal immediate release fentanyl ("TIRF"), approved by the Food and Drug Administration ("FDA") *for the single use of managing breakthrough cancer pain* in patients tolerant to around-the-clock opioid therapy. TIRF medications are extremely powerful narcotics that carry a high risk of addiction and potential death.

19. The FDA's concerns about TIRF drugs (including Subsys) were so great that it mandated the creation of a special program for prescribers, users and dispensing pharmacies known as Risk Evaluation and Mitigation Strategy ("REMS").

20. As a condition of his participation in the TIRF- REMS program, Defendant was required to complete an educational program regarding TIRF medication use. Defendant was also required to complete a knowledge assessment, and then complete an enrollment form where Defendant acknowledged that TIRF medications, including Subsys, **were only approved and indicated for use in patients suffering from breakthrough *cance*r pain.**

21. Plaintiff has attempted to obtain a copy of the TIRF-REMS enrollment form executed and submitted by Dr. Baddick or on Dr. Baddick's behalf but has been unsuccessful in doing so. Based on information and belief, attached as Exhibit "A" is a copy of the enrollment form utilized by the TIRF-REMS program for prescribers seeking enrollment in the TIRF-REMS program during all times material to the allegations in this Complaint.

22. TIRF medicines are formulations of fentanyl. Fentanyl is **a powerful synthetic opioid analgesic** that is similar to morphine but is **50 to 100 times more potent**. The TIRF medication Subsys delivers fentanyl to its users via the oral mucosa (the mucus membrane lining the inside of the mouth). It is administered as an oral sublingual spray and its action is nearly instantaneous.

23. Subsys is the trade name for a fentanyl sublingual spray, (a TIRF) which was packaged in a single-dose spray device intended for oral sublingual (under the tongue) administration. At all times relevant to this Complaint, Subsys was manufactured and sold exclusively by Insys[1], an Arizona-based corporation, and was available in the following dosage strengths:100mcg, 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg and 1600mcg fentanyl solution.

[1] In 2019 Insys filed for Bankruptcy in Delaware. The Bankruptcy Court authorized the sale of Subsys to Wyoming based BTcP Pharma LLC, part of the MMB Healthcare network.

## C. THE FALSE CLAIMS ACT

24. The False Claims Act (FCA) provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A) [or] (B) . . .
>
> ….
>
> is liable to the United States Government [for statutory damages and such penalties as are allowed by law].

31U.S.C. § § 3729(a)(1)-(3) (2006), as amended by 31 U.S.C. § 3729(a)(1)(A)-(C) (2010).

25. The FCA further provides that "knowing" and "knowingly"

> (A) mean that a person, with respect to information—
>
> 1. (i) has actual knowledge of the information;
>
> 2. (ii) acts in deliberate ignorance of the truth or falsity of the information; or
>
> 3. (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud;

31 U.S.C. § 3729(b) (2006), as amended by 31 U.S.C. § 3729(b)(1) (2010).

26. The False Claims Act (hereinafter "FCA") , 31 U.S.C. § 3729(a)(1), provides that any person who violates the FCA is liable to the United States Government for three times the damages which the Government sustains because of the act of that person, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of the FCA 31 U.S.C. § 3729 and 28 C.F.R. § 85.3(a)(9).

## D. THE MEDICARE PROGRAM

27. Congress established the Medicare Program in 1965 to provide health insurance coverage for people aged 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395, et. seq.

28. Medicare is funded by the federal government and administered by the Centers for Medicare & Medicaid Services (CMS), which is part of the United States Department of Health and Human Services (HHS).

29. The Medicare program consists of four parts: A, B, C, and D. Defendant caused to be submitted claims under Medicare Part D.

30. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D.

31. Part D coverage is not provided within the traditional Medicare program. Medicare Part D is based on a private market model. Medicare contracts

with private entities known as Part D Plan "Sponsors" to administer prescription drug plans.

32. Part D benefits are delivered by a Part D Plan Sponsor, which is either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan (MA-PD plan), a Program of All-inclusive Care for the Elderly (PACE) organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

33. When a pharmacy dispenses a drug to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the Part D Plan Sponsor for the costs not paid by the beneficiary.

34. The Part D Plan Sponsor then notifies CMS that a drug has been dispensed to a Medicare Part D beneficiary through a data file called a Prescription Drug Event (PDE) record, which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy. Importantly, the PDE does not contain information regarding the patient's diagnosis or the reason why the drug was prescribed.

35. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received

from pharmacies. The data contained in PDEs are data related to payment of claims. The Integrated Data Repository (IDR) process date is the date when the PDE is transmitted to CMS, such that CMS is informed of the PDE by the Part D Plan Sponsor.

36. In addition, CMS uses the information in the PDE at the end of the payment year to reconcile its advance payments to the sponsor with actual costs the plan sponsor incurred. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" (April 27, 2006). https://www.hhs.gov/guidance/document/instructions-requirements-submitting-prescription-drug-event-data.

37. Throughout the year, CMS makes prospective payments to Part D Plan Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy designed to cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy; and (3) the reinsurance subsidy.

38. The direct subsidy (a monthly capitated payment) is paid to the Part D Plan Sponsor in the form of advance monthly payments equal to the Part D Plan's standardized bid, risk adjusted for health status as provided in 42 C.F.R. § 423.329(b), minus a monthly beneficiary premium as determined in 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan.

39. CMS also makes payments to the Part D Plan Sponsor for premium and cost sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R. § 423.780 and 42 C.F.R. § 423.782. Cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost Sharing Subsidies (LICS)" and are documented and reconciled using PDE data submitted to CMS.

40. Part D sponsors who fail to submit required claims-level information contained in the PDE to CMS risk having to return the monthly payments to CMS during reconciliation. *See* 42 C.F.R. § 423.343(b), (c)(2) and (d)(2). In addition, Part D Sponsors are responsible for correcting submitted PDE data they determine are erroneous. *See* "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" at 4 (April 27, 2006). https://www.hhs.gov/guidance/document/instructions-requirements-submitting-prescription-drug-event-data

41. After the close of the plan year, CMS is responsible for reconciling the prospective payments to the Part D Sponsor's actual allowable costs by relying upon data elements submitted by Sponsors in their PDE records and direct and indirect renumeration (IDR) data.

42. In order to receive Part D funds from CMS, Part D Plan Sponsors, their authorized agents, employees, and contractors are required to comply with all applicable federal laws, regulations, as well as CMS instructions.

43. By statute, all contracts between a Part D Plan Sponsor and CMS must include a provision whereby the Plan Sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

44. Medicare Part D Plan Sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 505(h)(1).

45. CMS regulations require that all subcontracts between Part D Plan Sponsors and downstream entities contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions, including the CSA. 42 C.F.R. § 423.505(i)(4)(iv).

46. A Part D Plan Sponsor is required by federal regulation to certify to the accuracy, completeness and truthfulness of all data related to the payment. This provision, entitled "Certification of data that determine payments," provides in relevant part, as follows:

> (1) General Rule. ***As a condition for receiving a monthly payment*** . . . ***the Part D Plan sponsor agrees that*** its chief executive officer (CEO) chief financial officer (CFO), or ***an individual*** delegated the authority to sign on behalf of one of these officers, . . ***must request payment under the contract on a document that certifies*** (based on best knowledge, information and belief) the ***accuracy, completeness, and truthfulness*** of all data related to payment.

. . .

> (2) [Part D Sponsor] Certification of Claims Data: The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, . . . must certify (based on best knowledge, information and belief) that the claims data it submits . . . are accurate, complete and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(1), (k)(3) and (k)(5) (emphasis added).

47. All approved Part D Plan Sponsors who received payment under Medicare Part D in benefit years relevant to this case submitted the required attestations for data submitted that related to payment. 42 C.F.R. § 423.505(k).

48. The "Certification of data that determines payments" provision of the applicable regulation further provides: "[i]f the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

49. Compliance with the requirement that PDE data submitted by the Plan Sponsor is "true, accurate, and complete" is a condition of payment to the Plan Sponsor under the Medicare Part D Program. *Id*. and 42 C.F.R. § 423.505(k)(5).

50. Medicare only covers drugs that are used for a medically accepted

indication, which means a use that is approved under the Food, Drug, and Cosmetic Act, or a use which is supported by one or more citations included or approved for inclusion in one of the specified compendia. 42 U.S.C. § 1395w-102(e)(1) & (e)(4); 42 U.S.C. § 1396r-8(g)(1)(B)(i) & (k)(6); 42 C.F.R. § 423.100.

51. PDEs submitted to Medicare for drugs that are not for a medically accepted indication do not contain accurate, complete and truthful information about all data related to payment.

52. Medicare only covers drugs that are dispensed upon a prescription. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.100. A "Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription." 42 C.F.R. § 423.104(h). A valid prescription must comply "with all applicable State law requirements constituting a valid prescription." 42 C.F.R. § 423.100.

53. Under Pennsylvania law, a "prescription" or "prescription order" is defined as:

> The term ''prescription'' or ''prescription order'' means an order for a controlled substance, other drug**,** or device for medication which is dispensed to or for an ultimate user, but does not include an order for a controlled substance, other drug**,** or device for medication which is dispensed for immediate administration to the ultimate user. For example, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription order.

28 PA. Code § 25.51.

54. Under Pennsylvania law a:

> A prescription for a controlled substance must be issued for a legitimate medical purpose by a licensed practitioner in the usual course of professional practice. The responsibility for proper prescribing of controlled substances is upon the practitioner but a corresponding responsibility rests with the pharmacist who dispenses the medication and interprets the directions of the prescriber to the patient.

28 PA Code § 25.52(a).

55. Part D plans may also exclude drugs from payment if the drugs are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve functioning of a malformed body part. 42 U.S.C. § 1395w-102(e)(3) (incorporating by reference 42 U.S.C. § 1395y(a)).

56. Prescriptions for controlled substances that are not issued for a legitimate medical purpose are not for "medically accepted indications" and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 1395w-102(e)(1).

57. Prescriptions for controlled substances that are not issued for a legitimate medical purpose are not "valid prescriptions" under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52, and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 423.104(h).

58. PDEs submitted to Medicare for controlled substances that are dispensed when not issued for a legitimate medical purpose by an individual

practitioner acting in the usual course of his or her professional practice do not contain accurate, complete and truthful information about all data related to payment.

59. During the relevant time period, Dr. Baddick wrote prescriptions for Subsys for a Medicare Plan D beneficiary that were not for medically accepted indications and were invalid prescriptions. These prescriptions were filled by DiPietro's pharmacy.

## E. THE TRICARE PROGRAM

60. TRICARE is a federal healthcare program that is administered by the Defense Health Agency (DHA), a component of the Department of Defense (DoD). TRICARE provides health care insurance for active-duty military personnel, military retirees, and military dependents. The funds used by TRICARE to pay medical claims of qualified individuals are appropriated funds. 32 C.F.R. § 199.1(e).

61. TRICARE offers its beneficiaries a prescription drug benefit. TRICARE beneficiaries may receive prescription drugs from three different sources: military treatment facilities, the TRICARE Mail Order Pharmacy, and retail pharmacies.

62. TRICARE will only pay "for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care. . . . However, TRICARE benefits cannot be authorized to support or maintain an

existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means." 32 C.F.R. § 199.4.

63. When a TRICARE beneficiary's prescription is submitted to a TRICARE network pharmacy, the pharmacy submits an electronic claim to the Pharmacy Benefit Manager (PBM) for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a ten-day hold to ensure the prescription medication is delivered to the patient (and not returned to the shelf by the pharmacy), the PBM sends a TRICARE Encounter Data (TED) record electronically to TRICARE. The TED record includes information regarding the prescription event, including the prescriber's identity, the date the prescription was written, the number of refills authorized, the number of times the prescription has been filled, the amount claimed for reimbursement, and information on drug coverage under TRICARE.

64. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment

to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank (FRB). The FRB then transfers funds to the PBM's bank account.

65. All pharmacies that provide services to TRICARE beneficiaries are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Billing for costs for non-covered services is included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(2). More specifically, under TRICARE regulations, "[m]isrepresentations of dates, frequency, duration, or description of services rendered, or of the identity of the recipient of the services or the individual who rendered the services" are "presumed to be fraud." *Id.* § 199.2(c)(6).

66. Prescriptions for controlled substances that are not for medically accepted indications are not covered by TRICARE.

67. During the relevant time period, Dr. Baddick wrote prescriptions for Subsys for a TRICARE beneficiary that were not for medically accepted indications and were invalid prescriptions. These prescriptions were filled by DiPietro's pharmacy.

68. Because it is not feasible for the TRICARE program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with TRICARE requirements and relies upon providers to submit truthful and accurate certifications and claims.

## V. FACTS

### A. INSYS THERAPEUTICS AND SUBSYS

69. Insys was a pharmaceutical company that developed and commercialized Subsys, a sublingual fentanyl spray. Subsys is classified by the FDA as a transmucosal immediate-release fentanyl ("TIRF") drug.

70. Subsys was approved by the U.S. Food and Drug Administration in 2012 to treat breakthrough pain in adult *cancer* patients who are opioid tolerant.

71. Insys developed a "speaker program" where Insys would recruit and pay prescribers of Subsys to give presentations on the drug during peer-to-peer lunches and dinners.

72. Dr. Baddick attended multiple Insys speaker program events in Pennsylvania. It is believed and therefore averred that during such presentations Dr. Baddick was made aware that that the only indication for Subsys was for breakthrough cancer pain in opioid tolerant patients.

73. Dr. Baddick also had a relationship with Insys sales representative John Cacciatore. As will be related later within this Complaint, John Cacciatore referred patient A.P. directly to Defendant, Dr. Baddick to obtain a prescription for Subsys, knowing that patient A.P. did not have an active cancer diagnosis, was not treating for cancer, and was not experiencing breakthrough pain secondary to a cancer diagnosis.

74. In order to prescribe Subsys, medical providers were required to enroll in the FDA's Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program.

75. Dr. Baddick completed and submitted a TIRF REMS Access Prescriber Enrollment Form and completed all training and the knowledge assessment required to enroll in the TIRF_REMS program as Dr. Baddick was approved to prescribe TIRF-REMS narcotics.

76. To be enrolled in the TIRF REMS Access Program a provider was required to acknowledge that she/he "reviewed the TIRF REMS Access Education Program, including Full Prescribing Information for each TIRF medicine, and I have completed the Knowledge Assessment."

77. By enrolling in the TIRF REMS Access Program, Respondent acknowledged having read the program's "Education Program," which states, among other things:

Appropriate Patient Selection

Indication

**TIRF medicines are indicated only for the management of
breakthrough pain in adult patients with cancer 18 years of age and
older who are already receiving and who are tolerant to regular
opioid therapy for underlying persistent cancer pain.**

. . .

TIRF medicines are contraindicated in opioid non-tolerant
patients because life-threatening respiratory depression and death
could occur at any dose in patients not taking chronic opioids.

Definition of Opioid Tolerance

Patients considered opioid-tolerant are those who are taking,
for one week or longer, at least:
- 60 mg oral morphine/day
- 25 mcg transdermal fentanyl/hour
- 30 mg oral oxycodone/day
- 8 mg oral hydromorphone/day
- 25 mg oral oxymorphone/day
- OR an equianalgesic dose of another oral opioid

**TIRF medicines are intended to be used only in the care of
opioid-tolerant patients with cancer and only by healthcare
professionals who are knowledgeable of, and skilled in, the use of
Schedule II opioids to treat cancer pain**.

78. To be enrolled in the TIRF REMS Access Program a provider was required to acknowledge that she/he understood "that TIRF medicines are indicated *only* for the management of breakthrough pain in patients *with cancer* . . ..".

79. At times relevant to this Complaint, Dr. Baddick was enrolled in the TIRF REMS Access Program.

80. Dr. Baddick was aware that Subsys was only approved by the FDA and indicated for the treatment of breakthrough *cancer* pain in adults who were opioid-tolerant and acknowledged through his TIRF-REMS enrollment that Subsys was *only* to be prescribed for break through cancer pain.

81. Dr. Baddick further provided sworn testimony in the matter of *A.P. v Peter J. Baddick, D.O., et al.* CCP – Carbon County, Docket No. 19-2590, that he knew that the only indication for a prescription of Subsys was breakthrough cancer pain in opioid tolerant patients. See: Exhibit "B", Deposition of Peter J. Baddick, D.O. at page 145, line 17 to page 146, line 2.

82. In 2015, Dr. Baddick began to prescribe Subsys to patients that did not have an active cancer diagnosis.

83. Moreover, to the extent that Dr. Baddick prescribed Subsys for "off-label" uses, the manner and dosages of the Subsys prescribed for patients grossly exceeded the dosage recommended by the manufacturer and the FDA, were

medically unnecessary, not medically indicated and posed a risk of significant harm and potential death to his patients.

84. The overwhelming weight of the medical evidence at all times relevant to this Complaint and presently, confirms that the only safe and medically recognized use of a TIRF substance is/was for the management of breakthrough pain in opioid-tolerant **cancer** patients. Dr. Baddick understood and knew that this was the indicated usage for TIRF medications and knowingly and intentionally prescribed the drug to patients that did not have an active cancer diagnosis and were not experiencing break through pain secondary to a diagnosis of cancer.

**B. DR. BADDICK'S PRESCRIPTION PRACTICES**

85. At times relevant to this Complaint, Dr. Baddick saw patients at his medical practice, Penn Medical Group, P.C., located at 2175 Blakeslee Boulevard, Lehighton, PA 18235. Dr. Baddick was the sole shareholder of the Penn Medical Group beginning in 1999.

86. Penn Medical Group, P.C. ceased operations on or about September 28, 2019.

87. As a DEA registered physician, Dr. Baddick had a legal responsibility to prescribe Schedule II drugs, including Subsys, in accordance with the CSA and Pennsylvania law.

88. As an enrolled provider in the TIRF-REMS program, Dr. Baddick had a duty to prescribe TIRF medications in accordance with the TIRF program guidelines and requirements.

89. At all times relevant to this Complaint, Dr. Baddick repeatedly prescribed Subsys, a Schedule II drug, to patients under circumstances and for indications that were not for a legitimate medical purpose in the usual course of professional practice under Pennsylvania law. These patients include the following:

**PATIENT M.G.**

90. At all times relevant to this Complaint, Patient M.G. was a Medicare Plan D beneficiary.

91. Dr. Baddick and/or other providers in his office had been treating M.G. since at least 2006.

92. Medical records maintained and provided by Dr. Baddick indicate that he saw M.G. on April 1, 2015, for "back pain". M.G. provided a history of having back pain for 25 years. MG stated that she had received 23 injections with pain management without success or relief. The progress notes reflect that during the time M.G. was seen by Dr. Baddick she had been diagnosed with chronic pain, herniated nucleus pulposus (lumbar) and gastroesophageal reflux disease among other medical conditions. On the April 1, 2015, visit, Dr. Baddick performed a

limited physical examination, (confined to heart, lungs and ears, nose, and throat ("ent")).

93. There is no indication in Dr. Baddick's records or those of Penn Medicine that M.G. was ever diagnosed with cancer or that she was opioid tolerant.

94. There is no indication in Dr. Baddick's April 1, 2015, record that M.G. was prescribed or using opioids as of the April 1, 2015, visit. In fact, Dr. Baddick specifically listed the medications that M.G. was taking at the time of her April 1, 2015, visit and no opioid medication was listed. The only analgesic medication that Dr. Baddick listed for M.G. during the April 1, 2015, visit was Ibuprofen 800mg. qid.

95. Despite that on April 1, 2015, there is no evidence that M.G. had an active cancer diagnosis and no indication that she had opioid tolerance, Dr. Baddick prescribed Subsys 200 mcg. 4 times a day ("qid") (30 units) to M.G. This dosage of Subsys was twice the recommended starting dose of Subsys for all patients except those cancer patients that were actively taking Actiq. The dosage instructions provided by the manufacturer (Insys) and approved by the FDA are as follows:

**2.1 Initial Dose**

SUBSYS is not bioequivalent with other fentanyl products. Do not convert patients on a mcg per mcg basis from other fentanyl products. There are no conversion directions available for patients on any other fentanyl products other than Actiq. (Note: This includes oral, transdermal, or parenteral formulations of fentanyl.)

**Patients on Actiq**

The initial dose of SUBSYS is always 100 mcg with the only exception of patients already using Actiq.

a. For patients being converted from Actiq, prescribers must use the Initial Dosing Recommendations for Patients on Actiq table below (Table 1). Patients must be instructed to stop the use of Actiq and dispose of any remaining units.

**Table 1. Initial Dosing Recommendations for Patients on ACTIQ**

| Current ACTIQ Dose (mcg) | Initial SUBSYS Dose (mcg) |
|---|---|
| 200 | 100 mcg spray |
| 400 | 100 mcg spray |
| 600 | 200 mcg spray |
| 800 | 200 mcg spray |
| 1200 | 400 mcg spray |
| 1600 | 400 mcg spray |

b. For patients converting from ***Actiq doses 400 mcg and below***, titration should be initiated with 100 mcg SUBSYS and should proceed using multiples of this strength.

c. For patients converting from ***Actiq doses of 600 and 800 mcg***, titration should be initiated with 200 mcg SUBSYS and should proceed using multiples of this strength.

d. For patients converting from ***Actiq doses of 1200 and 1600 mcg***, titration should be initiated with 400 mcg SUBSYS and should proceed using multiples of this strength.

**All Other Patients**

Individually titrate SUBSYS to a dose that provides adequate analgesia and minimizes side effects. The initial dose of SUBSYS to treat episodes of breakthrough cancer pain is **always** 100 mcg. **When prescribing, do not switch patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to SUBSYS** as SUBSYS is not equivalent on a mcg per mcg basis with any other fentanyl product *[see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)]*.

Prescribe an initial titration supply of 100 mcg SUBSYS units, which limits the number of units in the home during titration.

Avoid prescribing a higher dose until patients have used up all units to prevent confusion and possible overdose.

*See: Dosage and Administration Instructions, part 2.1 of the Instructions for Use of Subsys (Exhibit "C").*

96. At the time that Dr. Baddick issued the Subsys prescription to M.G. on April 1, 2015, he knew that M.G. was not experiencing break through cancer pain, that M.G. was not diagnosed with cancer and that the issuance of the prescription at a level 100% higher than the recommended dosage for patients with breakthrough

cancer pain was unnecessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

97. At the time that Dr. Baddick issued the prescription to M.G. for Subsys he knew that she was treating with a physiatrist at VSAS Orthopedics for her chronic back pain and that the plan of care for M.G. included the "limited use of pain medication".

98. M.G.'s April 1, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy $1,280.94 for the April 1st Subsys prescription written by Dr. Baddick.

99. On April 2, 2015, Dr. Baddick authorized his employee, Tiffany Schoch to sign an INSYS Reimbursement Center and Patient Authorization & Referral Form on his behalf certifying that M.G. had been diagnosed with degeneration of cervical intervertebral disc/degeneration of cervicothoracic intervertebral disc, chronic pain and chronic pain syndrome and that she was opioid tolerant.

100. Dr. Baddick knew when he authorized his employee Tiffany Schoch to sign the Patient Authorization & Referral Form that M.G was not opioid tolerant as is reflected in his April 1, 2015, note documenting that M.G. was not actively taking opioid medications.

101. Dr. Baddick's medical records indicate that he again saw M.G. on April 8, 2015. At the time of this visit, M.G. had filled the prescription for Subsys issued by Dr. Baddick on April 1, 2015.

102. The medical records of Dr. Baddick indicate that M.G. was being seen … "to F/U with back pain and to start new medication". The note further indicates that M.G. related that she had set up an appointment with a durable medical equipment supplier to obtain a brace for her chronic back pain. There is no indication in the records that Dr. Baddick performed a physical examination of the patient.

103. Dr. Baddick issued two prescriptions to M.G. on April 8, 2015, one for Ultram, 50 mg, by mouth ("po") every 4-6 hours; and one for Oxycodone, 5 mg po every 8-10 hours. There is no indication in Dr. Baddick's note whether M.G. was taking the Subsys prescribed on April 1, 2015, or what, if any, relief the Subsys was providing for M.G.'s chronic back pain. Despite this, Dr. Baddick issued two new prescriptions to M.G. for narcotic medications. There is no indication in Dr. Baddick's note that M.G. was diagnosed and being treated for cancer.

104. Dr. Baddick's medical records indicate that he saw M.G. on April 20, 2015, for follow up of back pain and new medication - Subsys. The progress notes indicate that M.G. was diagnosed with chronic pain syndrome and

makes no reference to M.G. having a cancer diagnosis. There is no indication in the records that Dr. Baddick performed a physical examination of the patient.

105. The progress notes for April 20, 2015, reflect that Dr. Baddick prescribed Subsys 1200 mcg. qid. (180 units) to M.G. Dr. Baddick also prescribed OxyContin 10 mg.; 12 tables po (by mouth) twice daily (bid).

106. Dr. Baddick issued a prescription written to M.G. for Subsys 1200 mcg. on April 17, 2015, prior to his evaluation of M.G. which did not occur until April 20, 2015.

107. The Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy on April 17, 2015. The prescription was issued to M.G. at a dosage 600% higher than her initial dosage, which as set forth in paragraph 91 was 100% higher than the initial dosage set forth in the product labelling and instructions for use. The manufacturer and the FDA made the following recommendations regarding titration of Subsys:

**2.2 Dose Titration**

a. From the 100 mcg initial dose, closely follow patients and change the dosage level until the patient reaches a dose that provides adequate analgesia using a single SUBSYS dose per breakthrough cancer pain episode with tolerable side effects. Patients should record their use of SUBSYS over several episodes of breakthrough cancer pain and review their experience with their physicians to determine if a dosage adjustment is warranted.

b. For each breakthrough pain episode treated, if pain is not relieved after 30 minutes, patients may take **ONLY ONE** additional dose of the same strength for that episode. Thus patients should take a maximum of two doses of SUBSYS for any breakthrough pain episode.

c. Patients MUST wait **at least 4 hours** before treating another episode of breakthrough pain with SUBSYS.

d. If there is a need to titrate to a 200 mcg dose, prescribe 200 mcg SUBSYS units.

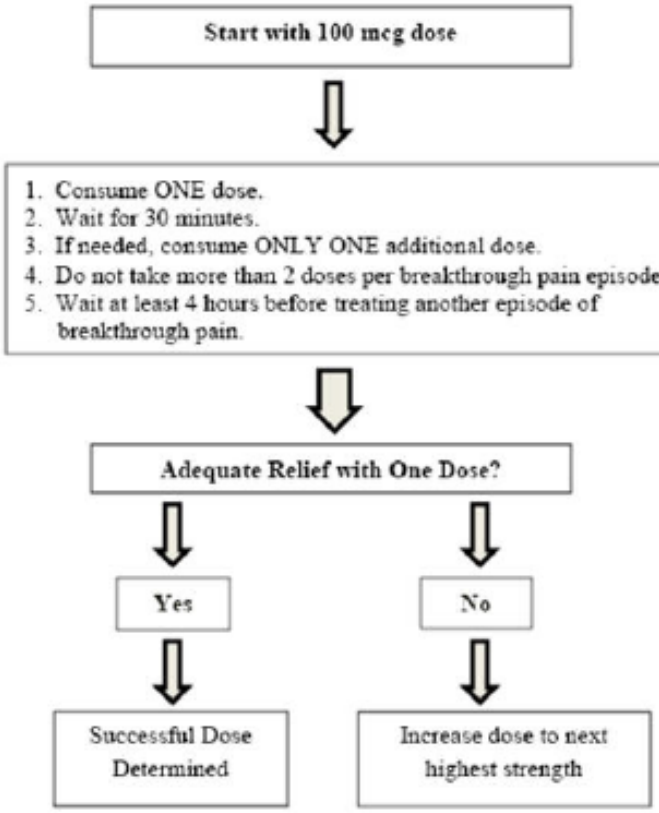
e. Subsequent titration steps are 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg. See Table 2.

f. To reduce the risk of overdose during titration, patients should have only one strength of SUBSYS available at any time.

**Table 2. Titration Steps**

| SUBSYS DOSE | Using |
|---|---|
| 100 mcg | 1 × 100 mcg unit |
| 200 mcg | 1 × 200 mcg unit |
| 400 mcg | 1 × 400 mcg unit |
| 600 mcg | 1 × 600 mcg unit |
| 800 mcg | 1 × 800 mcg unit |
| 1200 mcg | 2 × 600 mcg unit |
| 1600 mcg | 2 × 800 mcg unit |

**SUBSYS Titration Process**




**2.3 Maintenance Dosing**

Once titrated to a dose that provides adequate pain relief and tolerable side effects, patients should generally use **ONLY ONE** SUBSYS dose of the appropriate strength per breakthrough pain episode.

On those occasions when the breakthrough pain episode is not relieved within 30 minutes after administration of the SUBSYS dose, the patient may take **ONLY ONE** additional dose using the same strength for that episode.

Patients MUST wait **at least 4 hours** before treating another episode of breakthrough pain with SUBSYS. Once a successful dose has been found, patients should limit consumption to four or fewer doses per day.

108. There is no indication in the medical records of a legitimate medical purpose for the issuance of a prescription to M.G. for Subsys, notwithstanding elevating the dosage of Subsys by 600% to 1200 mcg. Dr. Baddick was aware that M.G. was not a cancer patient when he prescribed her Subsys on April 17, 2015 and was aware that the prescription was not medically necessary and not issued for a legitimate medical purpose. Moreover, Dr. Baddick issued the prescription for this potentially lethal dose of Subsys without seeing the patient to monitor the effects of the medication. The prescription for Subsys was therefore not a valid prescription.

109. M.G.'s April 17, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy $15,202.14 for the April 17th Subsys prescription written by Dr. Baddick.

110. An April 23, 2015, progress note indicates that M.G. called Dr. Baddick's office to express concern that she may be having a reaction to Subsys. M.G. reported that her heart rate was increased on April 22, 2015, and M.G. called an ambulance to her home.

111. Despite the patient's express concerns in her call on April 23, 2015, Dr. Baddick did not see M.G. until April 27, 2015. From the records provided by Dr. Baddick, this was a symptom specific visit for complaints of a productive cough, bilateral ear pain and a sore throat. There is no indication that Dr. Baddick assessed

M.G. for her chronic back pain on April 27, 2015, or that he assessed her narcotic medication use including her use of Subsys.

112. Dr. Baddick saw M.G. on May 6, 2015. From the records provided by Dr. Baddick, this was again a symptom specific visit for complaints of persistent cough, sore throat, vomiting and fever. There is no indication that Dr. Baddick assessed M.G. for her chronic back pain on May 6, 2015, or that he assessed her narcotic medication use, including her use of Subsys.

113. On or about May 12, 2015, DiPietro's pharmacy submitted a claim to Medicare Part D for a prescription of Subsys 1200 mcg (180 units) written by Dr. Baddick. Medicare paid the pharmacy $15,146.14. for the aforementioned Subsys prescription. Dr. Baddick has not provided any medical records that document that he evaluated M.G. regarding her chronic pain and the effects of her narcotic pain medication between his evaluation on April 20, 2015, and the issuance of the May 12, 2015, Subsys prescription.

114. Dr. Baddick's records do not indicate that M.G. was being treated for cancer or that she had been diagnosed with cancer. At the time Dr. Baddick issued the May 12, 2015, prescription he knew that the prescription that he issued for Subsys was not medically necessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

115. Moreover, the manufacturer (Insys) and the FDA made the following recommendations for maintenance dosing of Subsys:

> Dosage adjustment of SUBSYS may be required in some patients in order to continue to provide adequate relief of breakthrough pain.
>
> If signs of excessive opioid effects appear following administration of a single SUBSYS dose, subsequent doses should be decreased.
>
> Generally, only increase the SUBSYS dose when a single administration of the current dose fails to adequately treat the breakthrough pain episode for several consecutive episodes.
>
> If the patient experiences greater than four breakthrough pain episodes per day, the dose of the maintenance (around-the-clock) opioid used for persistent pain should be re-evaluated. In addition, if pain worsens, re-evaluate the patient for changes in the underlying pain condition.

> **2.3 Maintenance Dosing**
>
> Once titrated to a dose that provides adequate pain relief and tolerable side effects, patients should generally use **ONLY ONE** SUBSYS dose of the appropriate strength per breakthrough pain episode.
>
> On those occasions when the breakthrough pain episode is not relieved within 30 minutes after administration of the SUBSYS dose, the patient may take **ONLY ONE** additional dose using the same strength for that episode.
>
> Patients MUST wait **at least 4 hours** before treating another episode of breakthrough pain with SUBSYS. Once a successful dose has been found, patients should limit consumption to four or fewer doses per day.

According to Dr. Baddick's medical records, Dr. Baddick did not evaluate the Maintenance Dosing criteria for M.G. prior to issuing the May 12, 2015, prescription.

116. Dr. Baddick's medical records indicate that he saw M.G. on May 18, 2015, for a monthly medication check and refills on prescriptions for OxyContin and Ambien. The medical notes reflect that M.G. told Dr. Baddick Subsys was working fine. Other than this notation recording the history obtained from the patient there is no indication that Dr. Baddick assessed the patient's response to her pain medications during this visit. Dr. Baddick performed a limited

physical examination, confined to heart, lungs and ears, nose, and throat ("ent"). There is no indication that he examined M.G.'s back or her musculoskeletal system. Dr. Baddick issued a prescription to M.G. for OxyContin 10 mg. qid.

117. On or about June 2, 2015, DiPietro's pharmacy submitted a claim to Medicare Part D for a prescription of Subsys 1200 mcg (240 units) written for M.G. by Dr. Baddick. Medicare paid the pharmacy $20,194.60 for the aforementioned Subsys prescription.

118. There is no medical record produced by Dr. Baddick that correlates time wise with the June 2, 2015, Subsys prescription. There is no indication in the record that M.G. was diagnosed or being treated for cancer in June 2015. There is no indication in the record that Dr. Baddick assessed M.G.'s pain prior to issuing the prescription for Subsys on June 2, 2015. There is no indication in the record that Dr. Baddick performed a physical examination of M.G. prior to issuing the June 2, 2015, Subsys prescription.

119. Dr. Baddick provided a prescription written to M.G. for Subsys 1200 mcg dated June 1, 2015. Dr. Baddick was aware that M.G. was not a cancer patient when he prescribed her Subsys on June 1, 2015 and was aware that the prescription was not medically necessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

120. Dr. Baddick's medical records indicate that he saw M.G. on June 24, 2015, for a monthly medication check and refills on prescriptions for OxyContin and Subsys. The medical notes again reflect that M.G. was being treated for chronic pain syndrome and back pain. There is no indication that M.G. was being treated for or was diagnosed with cancer. There is no indication that Dr. Baddick assessed the patient's response to her pain medications during this visit.

121. On June 24, 2015, Dr. Baddick prescribed Subsys 1200 mcg 4 times a day (240 units) to M.G. and OxyContin 10 mg bid (twice per day). The prescription for Subsys was not medically necessary and was not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

122. M.G.'s June 24, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy $20,194.60 for the June 24th Subsys prescription written by Dr. Baddick.

123. Dr. Baddick's medical records indicate that he saw M.G. on July 22, 2015, for a monthly medication check and prescription refill for Ambien. Progress notes reflect that M.G. stated that a Subsys prescription would need to be called into the pharmacy on July 24, 2015, and OxyContin on August 17, 2015. The medical notes again reflect that M.G. was being treated for chronic pain syndrome and back pain.

124. There is no indication in Dr. Baddick's records on July 22, 2015, that M.G. was being treated for or was diagnosed with cancer. There is no indication that Dr. Baddick assessed the patient's response to her pain medications during this visit. There is no indication that Dr. Baddick performed a physical examination of the patient on this visit.

125. On July 22, 2015, Dr. Baddick prescribed Subsys 1200 mcg, 240 units qid and OxyContin 10 mg. bid. At the time Dr. Baddick issued the July 22, 2015, prescription for Subsys he knew that it was not medically necessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

126. M.G.'s July 22, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy $23,161.25 for the July 22nd Subsys prescription written by Dr. Baddick.

127. Dr. Baddick's medical records indicate that he saw M.G. on August 19, 2015, for a monthly medication check and prescription refills for Subsys, Ambien and OxyContin. The medical notes again reflect that M.G. was being treated for chronic pain syndrome and back pain. There is no indication that M.G. was being treated for or was diagnosed with cancer. Other than a notation "stable on meds", there is no indication that Dr. Baddick assessed the patient's response to her

pain and/or narcotic medications during this visit. There is no indication that Dr. Baddick performed a physical examination of the patient on this visit. Dr. Baddick issued prescriptions for OxyContin 10 mg, 60 tablets bid; Ambien 10 mg 30 tablets qid and Subsys 1200 mcg 240 units qid.

128. At the time Dr. Baddick issued the August 19, 2015, prescription for Subsys he knew that it was not medically necessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

129. M.G.'s August 19, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy $23,161.25 for the August 19th Subsys prescription written by Dr. Baddick.

130. Dr. Baddick's medical records indicate that he saw M.G. on September 16, 2015, for a monthly medication check and a prescription refill for OxyContin. The medical record for this encounter reveals that M.G. had a history of "drug abuse". There is no indication that M.G. was being treated for or was diagnosed with cancer. Physical examination findings recorded by Dr. Baddick included the following:

**Musculoskeletal**
**Spine/ Ribs/ Pelvis**
**Lumbosacral Spine - Examination of the lumbosacral spine reveals -** no tenderness to palpation, no pain, no swelling, edema or erythema of surrounding tissue and normal lumbosacral spine movements.
**Upper Extremity** - Note: Physiological ROM.

**Lower Extremity** - Note: Physiological ROM.

131. Dr. Baddick prescribed OxyContin 10 mg; 60 tablets; bid. There is no indication in the progress note for this office visit that Dr. Baddick prescribed Subsys.

132. Despite the absence of a notation in the progress note, on September 16, 2015, Dr. Baddick prescribed Subsys 1200 mcg. qid (240 units) to M.G. At the time Dr. Baddick issued the September 16, 2015, prescription for Subsys he knew that it was not medically necessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

133. M.G.'s September 16, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy $23,161.25 for the September 16th Subsys prescription written by Dr. Baddick.

134. Dr. Baddick's medical records indicate that he saw M.G. on October 12, 2015, for a monthly medication check and a prescription refill for OxyContin. The medical notes reflect that M.G. was being treated for chronic pain syndrome and back pain. Her past medical history includes a history of "drug abuse". There is no indication that M.G. was being treated for or was diagnosed with cancer. Physical examination findings recorded by Dr. Baddick included the following:

**Musculoskeletal** Not Present- Back Pain, Joint Pain and Myalgia.

**Musculoskeletal**
**Spine/ Ribs/ Pelvis**
**Lumbosacral Spine - Examination of the lumbosacral spine reveals -** no tenderness to palpation, no pain, no swelling, edema or erythema of surrounding tissue and normal lumbosacral spine movements.

135. On October 12, 2015, Dr. Baddick prescribed Subsys 1200 mcg. qid (240 units) to M.G. At the time Dr. Baddick issued the October 12, 2015, prescription for Subsys he knew that it was not medically necessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

136. M.G.'s October 12, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy $23,161.25 for the October 12th Subsys prescription written by Dr. Baddick.

137. Dr. Baddick's medical records indicate that he saw M.G. on November 2, 2015, for a monthly medication check and prescription refills for OxyContin, Ambien and Subsys. The medical notes reflect that M.G. was being treated for chronic pain and had a history of "drug abuse." There is no indication that M.G. was being treated for or was diagnosed with cancer. Physical examination findings recorded by Dr. Baddick included the following:

**Musculoskeletal** Not Present- Back Pain, Joint Pain and Myalgia.

**Musculoskeletal**
**Spine/ Ribs/ Pelvis**
**Lumbosacral Spine - Examination of the lumbosacral spine reveals -** no tenderness to palpation, no pain, no swelling, edema or erythema of surrounding tissue and normal lumbosacral spine movements.
**Upper Extremity** - Note: Physiological ROM.

**Lower Extremity** - Note: Physiological ROM.

138. On November 2, 2015, Dr. Baddick prescribed Subsys 1200 mcg. qid (240 units) to M.G. He also prescribed OxyContin 10 mg; 60 tablets; bid. At the time Dr. Baddick issued the November 2, 2015, prescription for Subsys he knew that it was not medically necessary and not issued for a legitimate medical purpose. Dr. Baddick was aware that M.G. was not a cancer patient when he prescribed her Subsys on June 1, 2015 and was aware that the prescription was not medically necessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

139. M.G.'s November 2, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy $23,161.25 for the November 2nd Subsys prescription written by Dr. Baddick.

140. On December 1, 2015, Dr. Baddick prescribed Subsys 1200 mcg (240 units) to M.G. Dr. Baddick was aware that M.G. was not a cancer patient when he prescribed her Subsys on December 1, 2015 and was aware that the prescription was not medically necessary and not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

141. M.G.'s December 1, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to Medicare

Part D. Medicare Part D paid the pharmacy $23,161.25 for the December 1st Subsys prescription written by Dr. Baddick.

142. There is no medical record produced by Dr. Baddick that correlates time wise with the December 1, 2015, Subsys prescription. There is no indication in the record that M.G. was diagnosed or being treated for cancer on December 1, 2015. There is no indication in the record that Dr. Baddick assessed M.G.'s pain prior to issuing the prescription for Subsys on December 1, 2015. There is no indication in the record that Dr. Baddick performed a physical examination of M.G. prior to issuing the December 1, 2015, Subsys prescription. There is no indication in the record that Dr. Baddick even saw M.G. on December 1, 2015.

143. Dr. Baddick's medical records indicate that he saw M.G. on December 22, 2015, and that M.G. was being seen for Subsys withdrawal. The progress notes reflect that M.G. had been out of Subsys since December 18, 2015. M.G. admitted using more Subsys in December than usual. M.G. requested to discuss other pain management strategies and stated she did not want to take medications with withdrawal reactions.

144. The progress notes of December 22, 2015, reflect that M.G. was complaining of shortness of breath, chest pain, hot and cold flashes, and felt like bugs were crawling on her skin.

145. The December 22, 2015, progress note assessment and plan states that Dr. Baddick's impression was that M.G. was experiencing opioid withdrawal and polysubstance abuse.

146. The December 22, 2015, progress note stated that M.G. would discontinue Subsys as of December 22, 2015.

147. Dr. Baddick's medical records indicate that he saw M.G. on December 29, 2015, and that M.G. was being seen to follow up on Subsys withdrawal. The progress notes reflect that M.G. reported feeling better and did not want to take Subsys.

148. The December 29, 2015, progress note assessment and plan states that Dr. Baddick's impression was that M.G. was feeling better after discontinuing Subsys and was no longer experiencing withdrawal symptoms.

149. All of Dr. Baddick's prescriptions for Subsys to Patient M.G. from April of 2015 through December of 2015 are identified below:

| **Date RX Filled** | **Details/Dosage** | **Paid by Medicare** |
|---|---|---|
| 4/9/2015 | Subsys 200 mcg | $1,280.94 |
| 4/17/2015 | Subsys 1,200 mcg | $15,202.14 |
| 5/12/2015 | Subsys 1,200 mcg | $15,202.14 |
| 6/2/2015 | Subsys 1,200 mcg | $20,194.60 |
| 6/25/2015 | Subsys 1,200 mcg | $20,194.60 |
| 7/22/2015 | Subsys 1,200 mcg | $23,161.25 |

| | | |
|---|---|---|
| 8/19/2015 | Subsys 1,200 mcg | $23,161.25 |
| 9/16/2015 | Subsys 1,200 mcg | $23,161.25 |
| 10/12/2015 | Subsys 1,200 mcg | $23,161.25 |
| 11/2/2015 | Subsys 1,200 mcg | $23,161.25 |
| 12/1/2015 | Subsys 1,200 mcg | $23,161.25 |
| | ***TOTAL*** | **$210,985.95** |

150. M.G. never had a cancer diagnosis while treating with Dr. Baddick. The issuance of prescriptions for Subsys were not medically indicated by the patient's diagnoses. Dr. Baddick prescribed Subsys to M.G. without a legitimate medical purpose and outside the usual course of professional practice. Therefore, none of the Subsys prescriptions Dr. Baddick wrote for M.G. were valid, lawful prescriptions under Pennsylvania law or federal regulations as identified above.

**PATIENT A.P.**

151. At times relevant to this Complaint, Patient A.P. was a TRICARE beneficiary.

152. John Cacciatore, an Insys sales representative was advised by a mutual acquaintance with A.P. that A.P. suffered from sarcoidosis.

153. Sarcoidosis is not cancer.

154. In June of 2015, John Cacciatore visited A.P. at her home.

155. During the visit to A.P.'s home, John Cacciatore recommended that A.P. make an appointment with Dr. Baddick to obtain a Subsys prescription.

156. At the time of John Cacciatore's visit to A.P.'s home, A.P. was not a patient of Dr. Baddick. In fact, at the time of Cacciatore's visit, A.P. was unfamiliar with Dr. Baddick.

157. A.P.'s first medical appointment with Dr. Baddick was June 10, 2015.

158. On June 10, 2015, Dr. Baddick saw A.P. for the first time. Medical records maintained by Dr. Baddick state that A.P. would like a prescription for Subsys. Dr. Baddick hand wrote on A.P.'s HPI (history of present illness) that "patient's main problem is diffuse chronic pain from fibromyalgia, sarcoidosis, Raynaud's syndrome and endometriosis". The Adult Health History for NEW Patients completed by A.P. on June 10, 2015, stated that the main reason for the visit was "chronic pain" and "to achieve a pain free normal life". The medical history completed by A.P. at the initial visit did not indicate that A.P. was currently treating or was currently diagnosed with cancer.

159. The medical records reflect, and Dr. Baddick's sworn testimony reveal that Dr. Baddick's was treating A.P. for chronic pain syndrome secondary to fibromyalgia, sarcoidosis, endometriosis, Raynaud's phenomenon, rheumatoid (arthritis) and "djd" (degenerative joint disease). He was not treating her for multiple myeloma. See: Exhibit "B"; Deposition of Peter J. Baddick, D.O. at page 145, lines 6 to 16.

160. As noted, A.P. first appointed with Dr. Baddick on June 10, 2015. The medical records indicate that Dr, Baddick advised A.P. that she should discontinue her Oxycodone prescription and that Dr. Baddick would obtain old records [medical records from A.P.'s other health care providers].

161. During her initial appointment, Dr. Baddick prescribed A.P. Subsys 200 mcg; qid. (120 units) He also issued a prescription for OxyContin 20 mg; 60 tablets, bid to A.P. This dosage of Subsys was twice the recommended starting dose of Subsys for all patients except those patients that were actively taking Actiq. The dosage instructions provided by the manufacturer (Insys) and approved by the FDA are as follows:

**[remainder of page intentionally left blank]**

**2.1 Initial Dose**

SUBSYS is not bioequivalent with other fentanyl products. Do not convert patients on a mcg per mcg basis from other fentanyl products. There are no conversion directions available for patients on any other fentanyl products other than Actiq. (Note: This includes oral, transdermal, or parenteral formulations of fentanyl.)

**Patients on Actiq**

The initial dose of SUBSYS is always 100 mcg with the only exception of patients already using Actiq.

a. For patients being converted from Actiq, prescribers must use the Initial Dosing Recommendations for Patients on Actiq table below (Table 1). Patients must be instructed to stop the use of Actiq and dispose of any remaining units.

**Table 1. Initial Dosing Recommendations for Patients on ACTIQ**

| Current ACTIQ Dose (mcg) | Initial SUBSYS Dose (mcg) |
|---|---|
| 200 | 100 mcg spray |
| 400 | 100 mcg spray |
| 600 | 200 mcg spray |
| 800 | 200 mcg spray |
| 1200 | 400 mcg spray |
| 1600 | 400 mcg spray |

b. For patients converting from ***Actiq doses 400 mcg and below***, titration should be initiated with 100 mcg SUBSYS and should proceed using multiples of this strength.

c. For patients converting from ***Actiq doses of 600 and 800 mcg***, titration should be initiated with 200 mcg SUBSYS and should proceed using multiples of this strength.

d. For patients converting from ***Actiq doses of 1200 and 1600 mcg***, titration should be initiated with 400 mcg SUBSYS and should proceed using multiples of this strength.

**All Other Patients**

Individually titrate SUBSYS to a dose that provides adequate analgesia and minimizes side effects. The initial dose of SUBSYS to treat episodes of breakthrough cancer pain is **always** 100 mcg. **When prescribing, do not switch patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to SUBSYS** as SUBSYS is not equivalent on a mcg per mcg basis with any other fentanyl product *[see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)]*.

Prescribe an initial titration supply of 100 mcg SUBSYS units, which limits the number of units in the home during titration.

Avoid prescribing a higher dose until patients have used up all units to prevent confusion and possible overdose.

*See: Dosage and Administration Instructions, part 2.1 of the Instructions for Use of Subsys (Exhibit "C").*

162. On June 11, 2015, Dr. Baddick authorized his employee, Tiffany Schoch to sign an INSYS Reimbursement Center and Patient Authorization & Referral Form on his behalf certifying that A.P, had been diagnosed with cancer, specifically ICD 135 or sarcoidosis. He also certified that A.P. was diagnosed with

"Other chronic pain" (ICD 338.29; "Chronic Pain Syndrome" (ICD 338.4) "other" (specifying ICD 203.0 or "multiple myeloma without mention of having achieved remission" and endometriosis (ICD-9; 203).

163. At the time that Dr. Baddick issued the Subsys prescription to A.P. on June 10, 2015, he did so knowing, or with reckless disregard for knowledge as to whether patient A.P. was opioid tolerant and with knowledge that A.P. did not have an active cancer diagnosis. Again, sarcoidosis is not cancer and there is no indication that A.P. was actively treating for multiple myeloma.

164. Dr. Baddick never requested, received or reviewed any prior medical records for patient A.P. He never confirmed that she had been prescribed opioids or was opioid tolerant. He never confirmed that she was diagnosed with multiple myeloma or that she had an active cancer diagnosis.

165. At the time Dr. Baddick issued the June 10, 2015, prescription for Subsys he knew that the issuance of the Subsys prescription at a level twice the recommended dosage was not medically necessary and was not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

166. A.P.'s June 10, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to TRICARE.

TRICARE paid the pharmacy $5,502.13 for the June 10th Subsys prescription written by Dr. Baddick.

167. On or about June 22, 2015, Dr. Baddick instructed or allowed a medical assistant in his office to prepare a prescription for Subsys 1200 mcg. (240 units) for A.P.

168. Dr. Baddick signed or authorized a prescription dated June 22, 2015, for Subsys 1,200 mcg; qid (240 units) to A.P. This was a 600% increase in the dosage of the Subsys initially prescribed, which initial prescription was twice the mandated dosage for cancer patients experiencing break through cancer pain. There is no indication that A.P. was being treated for or had an active diagnosis of cancer or was experiencing any pain associated with a diagnosis of cancer. Sarcoidosis is not cancer. The history of "follow-up for malignant myeloma" was not an active diagnosis and patient A.P. did not see Dr. Baddick for a follow-up for malignant myeloma. Indeed, neither the current or past box was checked where A.P. handwrote the words "follow-up for multiple myeloma". Dr. Baddick never requested, received, or reviewed any prior medical records for patient A.P. He never confirmed that she had been prescribed opioids or was opioid tolerant. He never confirmed that she was diagnosed with multiple myeloma or that she had an active cancer diagnosis.

169. There is no indication in Dr. Baddick's medical records that Dr. Baddick saw A.P. before issuing a prescription 600% higher in dosage than his initial prescription. There is no indication that Dr. Baddick assessed the patient's response to her pain medication prior to issuing the prescription. There is no indication that Dr. Baddick performed a physical examination of the patient prior to issuing the prescription. Dr. Baddick has not provided any records that indicate that he met with A.P. on or around June 22, 2015.

170. On June 22, 2015, Dr. Baddick also prescribed OxyContin 20mg; 60 tablets bid to A.P. At the time Dr. Baddick issued the June 22, 2015, prescription for Subsys to A.P. he knew that it was not medically necessary and was not issued for a legitimate medical purpose. The prescription was therefore not a valid prescription.

171. The manufacturer and the FDA made the following recommendations regarding titration of Subsys:

**2.2 Dose Titration**

a. From the 100 mcg initial dose, closely follow patients and change the dosage level until the patient reaches a dose that provides adequate analgesia using a single SUBSYS dose per breakthrough cancer pain episode with tolerable side effects. Patients should record their use of SUBSYS over several episodes of breakthrough cancer pain and review their experience with their physicians to determine if a dosage adjustment is warranted.

b. For each breakthrough pain episode treated, if pain is not relieved after 30 minutes, patients may take **ONLY ONE** additional dose of the same strength for that episode. Thus patients should take a maximum of two doses of SUBSYS for any breakthrough pain episode.

c. Patients MUST wait **at least 4 hours** before treating another episode of breakthrough pain with SUBSYS.

d. If there is a need to titrate to a 200 mcg dose, prescribe 200 mcg SUBSYS units.

e. Subsequent titration steps are 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg. See Table 2.



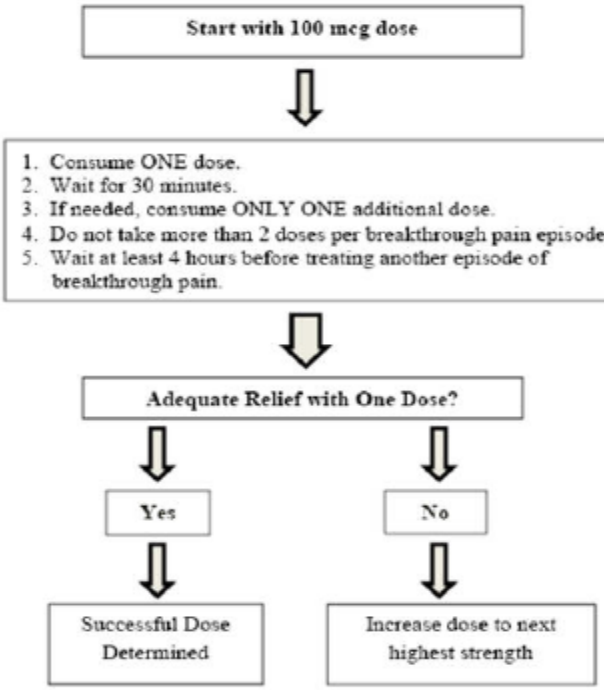


f. To reduce the risk of overdose during titration, patients should have only one strength of SUBSYS available at any time.

**Table 2. Titration Steps**

| SUBSYS DOSE | Using |
|---|---|
| 100 mcg | 1 × 100 mcg unit |
| 200 mcg | 1 × 200 mcg unit |
| 400 mcg | 1 × 400 mcg unit |
| 600 mcg | 1 × 600 mcg unit |
| 800 mcg | 1 × 800 mcg unit |
| 1200 mcg | 2 × 600 mcg unit |
| 1600 mcg | 2 × 800 mcg unit |

**SUBSYS Titration Process**



172. There is no indication in the medical records of a legitimate medical purpose for the issuance of an initial prescription for Subsys to A.P., let alone issuing another prescription and elevating the dosage of Subsys by 600% without even seeing the patient.

173. A.P.'s June 22, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy $20,798.68 for the June 22nd Subsys prescription written by Dr. Baddick.

174. Dr. Baddick's medical records indicate that he saw A.P. on July 8, 2015, for a medication check and prescription refills for OxyContin and Subsys. The medical notes state that A.P. was not due for a Subsys prescription until July 22, 2015. The medical notes also reflect that A.P. had active diagnoses of sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon. There is no indication in the records that A.P. was actively diagnosed with cancer or that she was seeing Dr. Baddick for cancer care or cancer pain. There is no indication in the records that Dr. Baddick performed a physical examination of A.P. on July 8, 2015.

175. On July 21, 2015, Dr. Baddick issued a prescription to A.P. for Subsys 600 mcg. qid (240 units). There is no indication that Dr. Baddick saw the patient before issuing the Subsys prescription. There is no indication that Dr. Baddick assessed the patient's response to her pain medication prior to issuing the

prescription. There is no indication that Dr. Baddick performed a physical examination of the patient prior to issuing the prescription. Dr. Baddick has not provided any records that indicate that he met with A.P. on or around July 22, 2015. Dr. Baddick also prescribed OxyContin 20mg; 60 tablets bid to A.P.

176. At the time Dr. Baddick issued the July 22, 2015, prescription for Subsys to A.P. he knew that it was not medically necessary and was not issued for a legitimate medical purpose. The prescription therefore was not a valid prescription.

177. A.P.'s July 21, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy $23,857.07 for the July 21st Subsys prescription written by Dr. Baddick to A.P.

178. Dr. Baddick's medical records indicate that he saw A.P. on August 3, 2015, for a monthly medication check and prescription refills for OxyContin and Subsys. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis and Raynaud's phenomenon. There is no indication in the records that A.P. was actively diagnosed with cancer or that she was seeing Dr. Baddick for cancer care or cancer pain. There is no indication in the records that Dr. Baddick performed a physical examination of A.P. on July 8, 2015. There is no indication in the records that Dr. Baddick assessed the patient's response to her pain medication prior to issuing the prescription.

179. On August 3, 2015, Dr. Baddick prescribed Subsys 600 mcg. qid (120 units) to A.P. Dr. Baddick also prescribed OxyContin 20 mg.; 60 tablets qid to A.P. on August 3, 2015. At the time Dr. Baddick issued the July 22, 2015, prescription for Subsys to A.P. he knew that it was not medically necessary and was not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

180. A.P.'s August 3, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy $11,918.66 for the August 3rd Subsys prescription written by Dr. Baddick.

181. Dr. Baddick's medical records indicate that he saw A.P. on August 31, 2015, for a monthly medication check and prescription refills. The notes reflect that A.P. expressed concerns regarding the risks of taking Subsys and had not taken Subsys for two days. A.P. also told Dr. Baddick that the OxyContin prescribed lasted 8 hrs. rather 12 hours. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon. There is no indication in the records that A.P. was actively diagnosed with cancer or that she was seeing Dr. Baddick for cancer care or cancer pain. Dr. Baddick performed a limited physical examination, (confined to heart, lungs and ears, nose and throat ("ent")) of A.P. on August 31, 2015. There is no indication in

the records that Dr. Baddick assessed the patient's response to her pain medication prior to issuing the prescription.

182. Notwithstanding, A.P.'s express concerns with the risks of continued Subsys usage, on August 31, 2015, Dr. Baddick again prescribed Subsys 600 mcg qid (120 units) to A.P. Dr. Baddick also prescribed OxyContin 20 mg; 60 tablets, bid. At the time Dr. Baddick issued the August 31, 2015, prescription for Subsys to A.P. he knew that it was not medically necessary and was not issued for a legitimate medical purpose. The prescription for Subsys was therefore not a valid prescription.

183. A.P.'s August 31, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy $11,891.66 for the August 31st Subsys prescription written by Dr. Baddick.

184. Prescription records for A.P. indicate that Dr. Baddick issued a prescription to A.P. for Lorazapam, a benzodiazepine medication that was filled on September 5, 2015. There is no indication in the medical records provided by Dr. Baddick of the issuance of this prescription.

185. Dr. Baddick's medical records indicate that he saw A.P. on September 28, 2015, for a monthly medication check and prescription refills. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon. There is no indication

in the records that A.P. was actively diagnosed with cancer or that she was seeing Dr. Baddick for cancer care or cancer pain. There is no indication in the records that Dr. Baddick performed a physical examination of A.P. on September 28, 2015. There is no indication in the records that Dr. Baddick assessed the patient's response to her pain medication prior to issuing the prescription.

186. On September 28, 2015, Dr. Baddick again prescribed Subsys 600 mcg qid (120 units) to A.P. Simultaneously Dr. Baddick increased A.P.'s OxyContin prescription from 20 mg. to 40 mg; 60 tablets, bid. At the time Dr. Baddick issued the September 28, 2015, prescription for Subsys to A.P. he knew that it was not medically necessary and was not issued for a legitimate medical purpose. The prescription was therefore an invalid prescription.

187. A.P.'s September 28, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy $11,819.66 for the September 28th Subsys prescription written by Dr. Baddick.

188. Dr. Baddick's medical records indicate that he saw A.P. on October 27, 2015, for a monthly medication check and prescription refills for OxyContin and Subsys. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's syndrome. The October 27, 2015, progress note indicates that A.P.'s pain level with

straight leg raising at the time of the appointment was 6/10; that at best her pain was 3/10 and at worst her pain 9/10. There is no indication in the chart that Dr. Baddick inquired of A.P. as to what circumstances caused exacerbation of her pain. There is no indication in the chart that Dr. Baddick inquired of A.P. whether the pain medications prescribed were effective in relieving her pain. There is no indication in the records that A.P. was actively diagnosed with cancer or that she was seeing Dr. Baddick for cancer care or cancer pain. Indeed Dr. Baddick has provided sworn testimony that he was not seeing A.P. for multiple myeloma. See: Exhibit "B"; Deposition of Peter J. Baddick, D.O. at page 145, lines 6 to 16.

189. According to the medical records for the October 17, 2015, visit. Dr. Baddick performed a limited physical examination and found all systems evaluated "WNL" (within normal limits"). There is no indication that he examined A.P.'s musculoskeletal system.

190. On October 27, 2015, Dr. Baddick prescribed Subsys 600 mcg. qid (120 units) to A.P. Dr. Baddick also maintained A.P.'s OxyContin prescription at 40 mg. 60 tablets, bid. At the time Dr. Baddick issued the October 27, 2015, prescription for Subsys to A.P. he knew that it was not medically necessary and was not issued for a legitimate medical purpose. The prescription for Subsys was therefore invalid.

191. A.P.'s October 27, 2015, Subsys prescription written by Dr. Baddick was filled by DiPietro's pharmacy and the pharmacy submitted a claim to

TRICARE. TRICARE paid the pharmacy $11,856.13 for the October 27th Subsys prescription written by Dr. Baddick.

192. Dr. Baddick's medical records indicate that he saw A.P. on November 25, 2015, for a monthly medication check and prescription refills for OxyContin and Subsys. The medical records again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon. There is no indication in the records that A.P. was actively diagnosed with cancer or that she was seeing Dr. Baddick for cancer care or cancer pain. There is no indication in the chart that Dr. Baddick performed a physical examination of A.P. on November 25, 2015.

193. On November 25, 2015, Dr. Baddick again prescribed Subsys 600 mcg; qid (120 units) to A.P. Dr. Baddick also issued a prescription to A.P. for OxyContin 40 mg.; 60 tablets; bid.

194. There is no record of A.P.'s November 25, 2015, Subsys prescription ever being filled.

195. Dr. Baddick's medical records indicate that he saw A.P. for her last medical appointment on December 16, 2015, for a monthly medication check and prescription refills. The medical notes reflect that A.P. informed Dr. Baddick that A.P. was no longer taking Subsys. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and

Raynaud's phenomenon. There is no indication in the records that A.P. was ever actively diagnosed with cancer or that she was seeing Dr. Baddick for cancer care or cancer pain. As per the averments in Paragraph 188, infra, Dr. Baddick has provided sworn testimony that he was not providing care to A.P. for multiple myeloma.

196. During the six months Dr. Baddick saw A.P., there is no record that Dr. Baddick ever requested or obtained records from any health care provider that had previously treated or was treating A.P.

197. During the six months Dr. Baddick saw A.P., there is no record that Dr. Baddick ever ordered blood work for A.P. Dr. Baddick only ordered urine drug screens for A.P., which would not show elevated levels of monoclonal protein Blood tests or urine tests that include protein levels would be required to confirm a diagnosis of multiple myeloma.

198. During the six months Dr. Baddick saw A.P., there is no record that Dr. Baddick ever ordered any diagnostic tests for A.P., beyond urine (drug) screens.

199. All of Dr. Baddick's prescriptions for Subsys to Patient A.P. from June of 2015 through October 2015 are identified below

| **Date RX Filled** | **Details/Dosage** | **Paid by Medicare** |
|---|---|---|
| 6/11/2015 | Subsys 200 mcg | $5,502.13 |
| 6/23/2015 | Subsys 1,200 mcg | $20,798.68 |
| 7/13/2015 | Subsys 600 mcg | $23,857.07 |
| 8/10/2015 | Subsys 600 mcg | $11,918.66 |
| 9/5/2015 | Subsys 600 mcg | $11,891.66 |
| 9/29/2015 | Subsys 600 mcg | $11,891.66 |

| | | |
|---|---|---|
| 11/4/2015 | Subsys 600 mcg | $11,856.13 |
| | ***TOTAL*** | **$97,715.99** |

200. A.P. did not have a cancer diagnosis. Subsys and all other TIRF medications are not and were not indicated for any of A.P.'s diagnoses. Dr. Baddick prescribed Subsys to A.P. without a legitimate medical purpose and outside the usual course of professional practice. Therefore, none of the Subsys prescriptions Dr. Baddick wrote for A.P. were valid, lawful prescriptions under Pennsylvania law.

**COUNT 1**

**False or Fraudulent Claims to Medicare 31 U.S.C. § 3729(a)(1)(A)) (previously 31 U.S.C. § 3729(a)(1)(1986))**

201. The United States repeats and realleges paragraphs 1 through 200 above.

202. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

203. Dr. Baddick knowingly, or with reckless disregard, caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). Specifically, Dr. Baddick caused a pharmacy to submit requests for payment to Medicare Part D Plan Sponsors for Subsys prescriptions that were false or fraudulent for two reasons. First, the Subsys prescriptions were not issued for a legitimate medical purpose and therefore not for "medically accepted indications," and thus not covered Medicare Part D drugs. 42

U.S.C. § 1395w-102(e)(1), referring to § 1395w-102(e)(4), which incorporates the definition of "medically accepted indication" found in § 1396r-8(k)(6). Second, Subsys was dispensed without a valid prescription under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52, because the prescriptions were not issued for a legitimate medical purpose by Dr. Baddick acting in the usual course of professional practice, and thus not covered Medicare drugs. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.104(h).

204. The Department of Justice, the agency responsible under the provisions of the False Claim Act with the responsibility to act on the fraud, learned of Dr. Baddick's actions upon the filing of a civil action against him by patient A.P. in the Court of Common Pleas of Carbon County, docketed to No. 19-250 on September 11, 2019. The Department became aware of the action by virtue of an article appearing in the Citizens Voice Newspaper on or about September 19, 2019.

205. Pursuant to 31 USCS § 3731(b):

> A civil action under section 3730 [31 USCS § 3730] may not be brought—
>
> **(1)** more than 6 years after the date on which the violation of section 3729 [31 USCS § 3729] is committed, or;
>
> **(2)** more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after

> the date on which the violation is committed, whichever occurs last.

31 USCS § 3731.

206. The instant action was timely brought because the Department of Justice instituted suit within three (3) years of the date when it was known by the Department of Justice of the existence of the claim. The instant suit was commenced on April 6, 2022.

207. For a false claim to be material, it must have a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. *Universal Health Services Inc. v. U.S. ex rel. Escobar 136 S.Ct. 1989, 2001-2002 (2016).*

208. By knowingly seeking payment for services provided in violation of material requirements of federal statutes and regulations, Dr. Baddick presented or caused to be presented false or fraudulent claims for payment to the United States. The requirements are material to the government's payment decisions because they relate directly to how much the government pays for services, to violations of express conditions of payment, and the government will not pay for medically unnecessary services. Every document submitted or statement made to the United States in connection with requests for payment is a false or fraudulent claim for payment or approval.

209. Because of Dr. Baddick's acts, the United States has suffered damages

in an amount to be determined at trial and is also entitled to treble damages under the False Claims Act, as well as a such civil penalties as are permitted by law, for each claim submitted to the Medicare Program.

**COUNT 2**

**False Statements to Medicare**
**31 U.S.C. § 3729(a)(1)(B)(previously 31 U.S.C. § 3729(a)(2)(1986))**

210. The United States repeats and realleges paragraphs 1 through 209 above.

211. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

212. Dr. Baddick knowingly caused to be made or used a false record or statement material to a false or fraudulent claim, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B). Specifically, Dr. Baddick caused a pharmacy to submit false information to Medicare Part D Plan Sponsors for Subsys prescriptions that were false or fraudulent for two reasons. First, the Subsys prescriptions were not issued for a legitimate medical purpose and therefore not for "medically accepted indications," and thus not covered Medicare Part D drugs. 42 U.S.C. § 1395w-102(e)(1), referring to § 1395w-102(e)(4), which incorporates the definition of "medically accepted indication" found in § 1396r-8(k)(6). Second, Subsys was dispensed without a valid prescription under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52 because the prescriptions were not issued for a legitimate medical

purpose by Dr. Baddick acting in the usual course of professional practice, and thus not covered Medicare drugs. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.104(h).

213. For a false claim to be material, it must have a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. *Universal Health Services Inc. v. U.S. ex rel. Escobar 136 S.Ct. 1989, 2001-2002 (2016).*

214. By knowingly seeking payment for services provided in violation of material requirements of federal statutes and regulations, Dr. Baddick presented or caused to be presented false or fraudulent claims for payment to the United States. The requirements are material to the government's payment decisions because they relate directly to how much the government pays for services, to violations of express conditions of payment, and the government will not pay for medically unnecessary services. Every document submitted or statement made to the United States in connection with requests for payment is a false or fraudulent claim for payment or approval.

215. Because of Dr. Baddick's acts, the United States suffered damages in an amount to be determined at trial and is also entitled to treble damages under the False Claims Act, as well as a such civil penalties as are permitted by law, for each claim submitted to the Medicare Program.

**COUNT 3**

**False or Fraudulent Claims to TRICARE 31 U.S.C. § 3729(a)(1)(A) (previously 31 U.S.C. § 3729(a)(1)(1986))**

216. The United States repeats and realleges paragraphs 1 through 215 above.

217. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

218. Dr. Baddick knowingly caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A). Specifically, Dr. Baddick caused a pharmacy to submit requests for payment to TRICARE for Subsys prescriptions that were false or fraudulent for two reasons. First, the prescriptions were not issued for a legitimate medical purpose and therefore not "medically necessary prescription drugs required in the treatment of an illness or injury," and thus not covered by TRICARE. 32 C.F.R. § 199.4. Second, Subsys was dispensed without a valid prescription under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52, because the prescriptions were not issued for a legitimate purpose by Dr. Baddick acting in the usual course of professional practice, and thus not covered TRICARE drugs.

219. For a false claim to be material, it must have a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. *Universal Health Services Inc. v. U.S. ex rel. Escobar 136 S.Ct. 1989, 2001-2002*

*(2016).*

220. By knowingly seeking payment for services provided in violation of material requirements of federal statutes and regulations, Dr. Baddick presented or caused to be presented false or fraudulent claims for payment to the United States. The requirements are material to the government's payment decisions because they relate directly to how much the government pays for services, to violations of express conditions of payment, and the government will not pay for medically unnecessary services. Every document submitted or statement made to the United States in connection with requests for payment is a false or fraudulent claim for payment or approval.

221. Because of Dr. Baddick's acts, the United States suffered damages in an amount to be determined at trial, and is also entitled to treble damages under the False Claims Act, as well as a such civil penalties as are permitted by law, for each claim submitted to TRICARE.

**COUNT 4**

**False Statements to TRICARE 31 U.S.C. § 3729(a)(1)(B) (previously 31 U.S.C. § 3729(a)(2)(1986))**

222. The United States repeats and realleges paragraphs 1 through 221 above.

223. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

224. Dr. Baddick knowingly caused to be made or used a false record or statement material to a false or fraudulent claim, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B). Dr. Baddick caused a pharmacy to submit false information to TRICARE for medications, including controlled substances, that were false or fraudulent for two reasons. First, the prescriptions were not issued for a legitimate medical purpose and therefore not "medically necessary prescription drugs required in the treatment of an illness or injury," and thus not covered by TRICARE. 32 C.F.R. § 199.4. Second, Subys was dispensed without a valid prescription under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52, because the prescriptions were not issued for a legitimate purpose by Dr. Baddick acting in the usual course of professional practice, and thus not covered TRICARE drugs.

225. For a false claim to be material, it must have a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. *Universal Health Services Inc. v. U.S. ex rel. Escobar 136 S.Ct. 1989, 2001-2002 (2016).*

226. By knowingly seeking payment for services provided in violation of material requirements of federal statutes and regulations, Dr. Baddick presented or caused to be presented false or fraudulent claims for payment to the United States. The requirements are material to the government's payment decisions because they relate directly to how much the government pays for services, to violations of express

conditions of payment, and the government will not pay for medically unnecessary services. Every document submitted or statement made to the United States in connection with requests for payment is a false or fraudulent claim for payment or approval.

227. Because of Dr. Baddick's acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act, as well as a such civil penalties as are permitted by law, for each claim submitted to TRICARE.

**PRAYER FOR RELIEF**

Wherefore, the United States demands and prays that judgment be entered in its favor and against Dr. Baddick as follows:

A. On Counts 1, 2, 3, and 4 for the amount of the United States' damages, trebled as required by law, and such penalties as are permitted by law, together with all such further relief as may be just and proper.

B. All other relief as may be required or authorized by law in the interests of justice.

**DEMAND FOR JURY TRIAL**

The United States demands a jury trial.

Respectfully,

GERARD M. KARAM
UNITED STATES ATTORNEY

Date: April 21, 2023

s/*B. Craig Black*
B. Craig Black
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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

| | | |
|---|---|---|
| UNITED STATES OF AMERICA, | ) | |
| | ) | CASE NO.: 3:22-CV-00512-KM |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | JUDGE MEHALCHICK |
| | ) | |
| PETER J. BADDICK, III., DO. | ) | |
| | ) | [ELECTRONICALLY FILED] |
| Defendant. | ) | |

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that she is an employee in the Office of the United States Attorney for the Middle District of Pennsylvania and is a person of such age and discretion as to be competent to serve papers. That on this Friday, April 21, 2023, she caused to be served a copy of the foregoing Amended Complaint by electronic means to his counsel of record, addressed as follows:

Conner McCabe, Esquire – cmccabe@frierlevitt.com

and, via email and first class mail, addressed as follows:

Jason N. Silberberg, Esquire – jsilberberg@frierlevitt.com

/s/ Samantha M. Deibert
SAMANTHA M. DEIBERT
Legal Assistant